



# GLUTARALDEHYDE

## Guidelines for Safe Use and Handling in Health Care Facilities

DIVISION OF ENVIRONMENTAL AND OCCUPATIONAL HEALTH SERVICES

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*Glutaraldehyde-based products are effective sterilants and disinfectants that are primarily used for medical devices that cannot be steam-sterilized, particularly heat-sensitive, lensed instruments that are commonly subjected to high-level disinfection between patient uses. If done properly, glutaraldehyde-based products can be used without adverse health effects. However, dermatologic and respiratory effects on exposed personnel have been reported; therefore, adequate precautions should be taken when using glutaraldehyde-based products. This document specifically addresses: 1) design considerations for areas in which glutaraldehyde is used, 2) proper work practices to help minimize occupational exposure to glutaraldehyde, 3) personnel qualifications, training, personal protective equipment, and health considerations, and 4) air monitoring for glutaraldehyde vapor.*

### WHAT IS GLUTARALDEHYDE?

Glutaraldehyde [CAS 111-30-8], or 1,5-pentanedial, is a dialdehyde that is slightly acidic in its natural state. In a buffered alkaline solution (pH 7.5-8.5) it is a highly effective microbiocidal agent. Alkaline glutaraldehyde is widely used in the cold sterilization of medical, surgical, and dental equipment (in products such as Cidex<sup>®</sup>, Aldesen<sup>®</sup>, Hospex<sup>®</sup>, Wavicide<sup>®</sup>, Procide<sup>®</sup>, Omnicide<sup>®</sup>, and Sonacide<sup>®</sup>). It is also used as a biocide for contaminated water in cooling towers and air-conditioning units. Besides its use as a biocide, glutaraldehyde is also used as an ingredient in X-ray developers, a tanning agent for leather, in the treatment of hyperhidrosis, as a tissue fixative in histochemistry and electron microscopy, as an embalming agent, and as a cross-linking agent in the preparation of microcapsules.

Glutaraldehyde is usually a clear liquid that turns green when activated. It has the sharp, pungent odor typical of all aldehydes, with an odor threshold of 0.04 parts per million (ppm).

### WHAT ARE THE HEALTH EFFECTS OF GLUTARALDEHYDE EXPOSURE?

Glutaraldehyde is a strong irritant to the skin, eyes, and respiratory system. Contact with solution can cause skin sensitization, leading to allergic contact dermatitis. Vapor inhalation has been implicated as a possible cause of occupational asthma. Glutaraldehyde can also aggravate pre-existing asthma and inflammatory or fibrotic pulmonary disease.

### WHAT IS THE OCCUPATIONAL EXPOSURE LIMIT?

The American Conference of Governmental Industrial Hygienists (ACGIH) has adopted a ceiling threshold limit value (TLV-C) of 0.05 ppm. A TLV-C represents an airborne concentration that should not be exceeded during any part of the work shift. The National Institute for Occupational Safety and Health (NIOSH) has

established a recommended exposure limit of 0.2 ppm, as a ceiling limit, for glutaraldehyde. The Occupational Safety and Health Administration (OSHA) had also established a permissible exposure limit (as a ceiling level) of 0.2 ppm in 1989, but this was vacated in 1993 for legal reasons. It is essential that health care personnel keep informed of the status of federal, state, and local regulations applicable to glutaraldehyde.

### **WHERE SHOULD GLUTARALDEHYDE BE USED?**

Glutaraldehyde should be used in separate designated areas where control can be exercised over ventilation; traffic; and proper equipment installation, operation, and maintenance.

### **GENERAL VENTILATION**

Rooms in which glutaraldehyde is to be used should be well ventilated and large enough to ensure adequate dilution of vapor, with a minimum air exchange rate of 10 air changes per hour. Ideally, local exhaust ventilation should be installed to control glutaraldehyde vapor.

### **LOCAL EXHAUST VENTILATION**

A local exhaust hood or a self-contained, free-standing system should be located at the point of glutaraldehyde vapor release. Vapor is collected in a suitable hood and either exhausted to the outside via a fan and duct system, or delivered to a filter system that captures or chemically inactivates the glutaraldehyde.

A properly functioning laboratory fume hood is a perfect example of an effective local exhaust ventilation system.

### **AUTOMATED PROCESSING EQUIPMENT**

Although automated glutaraldehyde processing equipment is designed to reduce exposures, adequate ventilation is still necessary because vapor can escape into the work area when solution is activated and loaded into the reservoir, or if it becomes necessary for the operator to open the system during mid-cycle.

### **STORAGE**

Unused glutaraldehyde solution should be stored in tightly closed, properly labeled containers in a cool, secure, and properly marked location.

### **DISPOSAL**

Glutaraldehyde solutions may be disposed of, along with copious amounts of cold water, into a drain connected to a sanitary sewer. Glutaraldehyde solutions should not be discarded into septic systems. Empty glutaraldehyde containers should be disposed of according to product label instructions, usually by rinsing with water and discarding as normal waste material.

### **PERSONAL PROTECTIVE EQUIPMENT**

Requirements pertaining to personal protective equipment (PPE) are specified in OSHA Standard 29 CFR 1910.132. The standard requires that a hazard assessment be conducted to determine what hazards necessitate the use of PPE. A written program on the proper use of PPE should be developed and implemented. Specific training must be provided to anyone required to wear PPE.

## Eye Protection

Eyes must be protected against contact with glutaraldehyde solution, and vapor levels must be controlled to prevent eye irritation. Splash-proof goggles and/or full face shields should be used whenever working with glutaraldehyde. Suitable eyewash units (conforming to American National Standards Institute (ANSI) Z358.1-1990) must be available (within 10 seconds travel time and/or 100 feet travel distance) for immediate emergency use in all locations where glutaraldehyde is used.

## Hand Protection

Hands should be protected from contact with glutaraldehyde solution. Nitrile and butyl rubber are the materials most impervious to glutaraldehyde. Polyethylene and spun-bonded polypropylene (e.g., Tyvek®) coated with polyethylene provide adequate protection for several hours. Polyvinyl chloride and neoprene do not provide adequate protection from glutaraldehyde. Latex gloves should not be used except where short-term incidental contact is expected, because the permeability of latex varies considerably depending on the manufacturer. They should only be worn in conjunction with additional hand protection. Employees should be aware that latex has been associated with the development of allergic reactions such as dermatitis and asthma.

## Body Protection

Isolation gowns, lab coats, or aprons and sleeve covers, which are made of appropriate protective materials, should be used to provide additional protection. Garments of this type are available in polyethylene-coated spun-bonded polypropylene.

Protective clothing should be removed immediately if it becomes saturated, and it should be laundered before reuse. If any skin contact with glutaraldehyde should inadvertently occur, the skin should be washed thoroughly with soap and water, and flushed with water for at least 15 minutes.

## Respiratory Protection

Appropriate respirators should be used by all employees who may be exposed above the TLV-C to glutaraldehyde vapor during routine or emergency work procedures. The respirators must be approved by NIOSH and appropriate for use with glutaraldehyde (i.e., air-purifying respirators must be fitted with organic vapor cartridges). Routine respirator usage is not an acceptable substitute for appropriate engineering, administrative, and work practice controls.

All personnel who may be required to wear a respirator must be included in a Respiratory Protection Program that meets the requirements of OSHA's Respiratory Protection Standard (29 CFR 1910.134). An acceptable respirator program must include standard written operating procedures covering all aspects of the program (i.e., workplace assessment; respirator selection; employee medical surveillance; procedures for inspection, cleaning, and storage of respirators; employee training; qualitative or quantitative fit-testing; and program evaluation). Employee training, medical surveillance, and program evaluation should be repeated annually.

## GLUTARALDEHYDE SPILLS

All spills have the potential to cause the ambient concentrations of glutaraldehyde vapor to exceed established exposure limits. The *Joint Commission on Accreditation of Healthcare Organizations* specifies under their Hazardous Materials Plan that a glutaraldehyde spill containment "response team" be created. The team should include a representative from the safety committee, a physician (ideally, an occupational health physician), the unit supervisor, and any other personnel deemed appropriate. The team will be responsible for developing and executing procedures for glutaraldehyde spills.

## **Spill Containment Plan**

A written plan for containment of glutaraldehyde spills should be prepared by the response team. Procedures should specify: 1) cleanup equipment, 2) placement of equipment for easy access, 3) a plan for alerting personnel, 4) recommendations for avoiding exposure to glutaraldehyde, and 5) evacuation of nonessential personnel. The plan should include: a) procedures for evacuating personnel in the event of a spill, b) procedures for medically treating persons who may have been overexposed to glutaraldehyde solution or vapor, c) procedures for reporting an emergency to appropriate authorities (e.g., health & safety office), d) procedures for material cleanup, specifying equipment and personal protective equipment, e) description of the employee training program and method(s) used to verify competency, f) the known rate of air exchanges in the spill area, g) the potential for the general ventilation system to carry glutaraldehyde vapor to other areas of the facility, and a prescribed course of action to prevent the dispersal of glutaraldehyde to other areas, h) the recommendations of the product manufacturer for emergency procedures, as specified in the material safety data sheet (MSDS) or obtained by calling the manufacturer's emergency phone number, i) description of the respiratory protection program, outlining the safe selection, use, location, storage, fit-testing, periodic inspection of emergency-use respirators, and procedures to be used for medical assessment of staff required to use respirators, and j) designation of the person(s) responsible for supervising the handling of glutaraldehyde spills.

## **Spill Cleanup Procedures**

Whether the use of inactivating chemicals and respiratory protection equipment is necessary will be determined by the glutaraldehyde concentration, volume of spill, the temperature of the room and solution, and the effectiveness of the ventilation in the area. The use of a

respirator is required for any spill with unknown vapor concentrations. Any spill larger than a drip or a splash may need to be inactivated.

## **Neutralizing Chemicals**

Several chemicals (e.g., sodium bisulfite, dibasic ammonium phosphate, household ammonia, ammonium carbonate powder) can be used to decrease the glutaraldehyde concentration in solutions and/or reduce ambient vapor levels in spill situations. There are also a number of commercially available products designed for this purpose. Such chemicals have varying degrees of activity; some are used to deal with the solution, some with vapor. Before using a glutaraldehyde-based product, health care personnel should be familiar with manufacturer's specific recommendations for chemicals used to clean up spills.

## **Drips and Splashes**

Drips and splashes should be immediately wiped up with a sponge, towel, or mop. Alternatively, the glutaraldehyde solution can be neutralized with an appropriate chemical agent, and then wiped up with a sponge, towel, or mop. The sponge, towel, or mop should be thoroughly rinsed with large amounts of water and the water discarded down a drain.

## **Large Spills**

Large spills may cause vapor levels to rapidly increase above the TLV-C. The spill should be cleaned up by a trained response team equipped with the appropriate respiratory protection, the appropriate personal protective equipment, and the necessary cleanup tools (i.e., mop, sponges, towels, squeegee, plastic dust pan, plastic scoop, and neutralizing chemical). Large spills should be contained and neutralized or contained and collected for disposal. Depending on the amount of solution and the environmental conditions, some heat and vapors may be liberated by the reaction with the neutralizing chemicals. After the glutaraldehyde solution is collected and disposed of, the area contaminated by the

solution should be thoroughly rinsed. Cleanup tools should also be thoroughly rinsed with water, which can then be flushed down a drain.

## **FIRST AID**

Personnel who come into contact with liquid glutaraldehyde should immediately remove contaminated clothing and shoes and thoroughly wash contaminated skin with flowing water. In the case of eye contact with liquid glutaraldehyde, the eyes should be flushed with copious amounts of water for at least 15 minutes. Contact lenses, if worn, should not be removed, because the protein cross-linking properties of glutaraldehyde may cause the lenses to become bound to the cornea. Exposed personnel should be evaluated by a physician immediately after the above emergency measures. Written policies and procedures should be established for emergency medical care of glutaraldehyde-exposed personnel.

## **PERSONNEL QUALIFICATIONS**

It is important that liquid chemical disinfection and sterilization processing be supervised and performed by knowledgeable personnel if worker safety, as well as the effectiveness of the disinfection/sterilization process, is to be ensured.

### **Supervisory Personnel**

Personnel assigned to supervisory functions should be prepared for this responsibility by formal training, experience, and continuing education. Suggested minimum qualifications include:

- 1) demonstration of current knowledge and adequate relevant experience in health care or hospital-related work; 2) participation in the health care facility's formal orientation and training programs (e.g., educational seminars, personnel and management programs, and courses directly related to the position). Special emphasis should be placed on personnel safety;

means of avoiding exposure to glutaraldehyde and other liquid chemical sterilants; safe use of liquid chemical sterilants, including applicable regulations and label directions; and decontamination, high-level disinfection, sterilization, and distribution of endoscopes and other medical devices; 3) participation in inservice programs designed specifically for the personnel performing the glutaraldehyde disinfection/sterilization process; 4) attendance at educational seminars and familiarity with the current literature on glutaraldehyde; and 5) demonstration and improvement of expertise through teaching and through participation in various committees within the health care facility, such as: procedural, infection control, safety, and hazardous materials.

### **Processing Personnel**

Personnel engaged in chemical disinfection or sterilization processing must receive initial orientation and on-the-job training. This training program should cover the policies and procedures of the health care facility, safety precautions, and appropriate personal protective equipment. Personnel must be informed of the potential health effects of exposure to glutaraldehyde, and they should be familiar with the information contained in the MSDS, which is required under the OSHA Hazard Communication Standard (29 CFR 1910.1200) to be made available to all workers using glutaraldehyde. This standard also requires that employees receive training regarding many aspects of other chemical hazards. Records, including the names of employees in attendance, should be maintained for the training programs conducted.

## **VAPOR MONITORING**

Glutaraldehyde vapor monitoring should be conducted to ensure a safe work environment and to establish compliance with recommended limits, such as the TLV-C, and voluntary guidelines on occupational exposure to glutaraldehyde. Several air sampling and monitoring techniques are available.

## **Monitoring Methods**

Some glutaraldehyde vapor monitoring methods must be performed or supervised by technically qualified personnel trained in air sampling strategies and monitoring techniques. Other methods may be less complex and, with instructions from the manufacturer, can be used reliably by competent health care personnel. Data on accuracy, sensitivity, reproducibility, and reliability of the method is necessary; and awareness of potential effects of interfering substances on the results must also be considered. Ideally, health care personnel should seek the advice of a certified industrial hygienist when designing a monitoring program.

The instructions for use provided by the vapor monitoring equipment and sampling apparatus manufacturers must be followed.

## **Monitoring Procedures**

Sampling should be conducted in all work areas where workers may be exposed to glutaraldehyde vapor; and should include personal breathing zone samples. Monitoring should take place during disinfection or sterilization procedures, and during worst case situations (i.e., when exposures are the highest over the shortest period of time).

To accurately assess a ceiling limit, exposure monitoring should be conducted during worst case situations, such as when solution is being activated, poured to or from containers, or agitated.

## **RECORDKEEPING**

If performed, employee breathing zone sampling must be documented and records maintained in a

designated location. The documentation should include: 1) the name and qualifications of the person or organization that conducted the monitoring, 2) the date the survey was performed, 3) the sampling and analytical method used, the test protocol, and instrumentation, 4) workplace ventilation system characteristics at the time of sampling, 5) the results (locations and measured glutaraldehyde concentrations), 6) any personal protective equipment worn, and 7) any recommendations for corrective actions.

Employees should be notified of their personal monitoring results within 15 days of receipt of the results, and a copy maintained in the employee's personnel file. OSHA requires that such records be maintained for at least 30 years. If employee breathing zone monitoring shows glutaraldehyde concentrations exceeding the TLV-C, corrective actions should be taken to reduce exposure levels.

## **MEDICAL SURVEILLANCE**

Employees who are exposed above the TLV-C, or exhibit symptoms of exposure to glutaraldehyde, should be provided with periodic medical examinations which include, at least: 1) a standardized questionnaire addressing occupational & medical history, pulmonary symptoms, and cigarette smoking, 2) a physical examination, and 3) pulmonary function testing.

OSHA requires that medical records be maintained for the duration of employment and for at least 30 years thereafter.

The American Thoracic Society can provide more thorough guidelines for the surveillance of respiratory hazards in the occupational setting.

*Much of the information in this booklet was extracted from the document “Safe use and handling of glutaraldehyde-based products in health care facilities” published by the Association for the Advancement of Medical Instrumentation (AAMI). This document, which has been approved as an American National Standard, provides much more detailed information intended to promote safe use and handling of glutaraldehyde as a disinfectant/sterilant in health care facilities, and to reduce personnel and patient exposure to the substance. The standard, ANSI/AAMI ST58-1996, is available from AAMI, 3330 Washington Blvd., Arlington, VA, 22201-4598, (703) 525-4890.*

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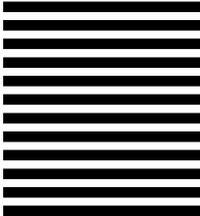
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